REMARKS/ARGUMENTS

In response to the Rejection mailed May 18, 2004, Applicants have canceled claims 2, 20-24, 26, 28 and 36, newly amended claims 1, 27, 29, 31, 32, 39, 41, and present the following remarks.

The amendments made above incorporate some of the examiner's suggestions and address the examiner's questions. Therefore, no new issues have been presented. Claims 1, 3-19, 25, 27, 29-35, 37-41 are pending.

Claims 1, 3-19 and 25, 27, 29-35 and 37-41 were rejected under 35 USC 112, second paragraph, as being indefinite.

Claim 1 was considered vague and indefinite by reciting "substantially all" in part (b). The examiner recommended deleting the recitation from the claims. Applicants have deleted this recitation making this rejection moot. Similar language was used in claim 41, which was amended accordingly.

Claim 1 was considered vague and indefinite in the recitation "greater than about 3kDa". The lowest cut-off and its functional purposes are discussed several times in the specification including page 20, line 4, page 27, lines 12-13, page 33, lines 2 and 7 and page 42, lines 15+. This type of language is well understood in the art to describe molecular weight ranges. Additionally, numerical values are inherently definite. On page 10 of the rejection mailed May 18, 2004, the examiner has discussed fractions having cut-offs of < or > 30 kDa. There appears to be some confusion because the < or > 30kDa has nothing to do with the "greater than about 3kDa". < or > about 30kDa refers to the cut-off between the "first" and the "second" fractions. Claim 1 discusses only the "first fraction", the one between about 3 and about 30. The "second fraction", the one between about 30 and about 75 is not discussed until claim 27.

Claim 1 was also considered vague and indefinite in the recitation "below about". Claim 1 is clear, but to further clarify the meaning claim 1 has been amended to explicitly define the magnitude of the molecular weight ranges.

Claim 27 was considered indefinite as to the nature of the ranges recited. Claim 27 is clear as to the definitions of the cut-offs used for the ranges. Furthermore, claim 27 has been amended in a rather wordy fashion to avoid any possible misunderstanding.

The examiner has questioned when the step recited in claim 38 occurs in the process. Claim 38 recites using the antibody and therefore occurs after the step in claim 37 where the antibody is generated. Please note that the "test body fluid" does not necessarily refer to the same material as the "body fluid" in claim 1.

Claims 1, 3-5, 8, 9, 12-14, 17, 25, and 29-37 were rejected under 35 USC 103(a) as being unpatentable over Stevens in view of Liu et al. Stevens was cited to show removing interfering macromolecules from a sample before analyzing the proteins contained in it. Liu et al was cited as showing removing salts and other metabolites below 6kDa before analyzing the proteins in the sample. The examiner contends it would have been obvious to combine both techniques into a combined method. This rejection is respectfully traversed.

Neither reference alone or in combination suggests using <u>any</u> top molecular weight cut-off. This is important to the present invention to detect kidney-filtered proteins as discussed throughout the specification.

The examiner has taken the rather odd interpretation that the language describing proteins "greater than 3kDa and below about 30,000" somehow includes all proteins including those above the specified range. While applicants disagree with this interpretation, the claims have been amended to add somewhat redundant language to prohibit such misinterpretation of the claims. Accordingly, this rejection should be withdrawn.

The examiner has also taken the position that claim 29 does not require plural specific binding agents. The examiner has argued that "plural" specific binding agents (note the plural form of the word "agents") could be two of the same agent with two different

properties. Applicants disagree with this interpretation but have amended claim 29 to avoid any possible misinterpretation. It should also be noted that none of the references use plural specific binding agents to remove corresponding plural proteins from the sample or a fraction thereof.

Still further, no combination of these references provides any suggestion to collect and analyze two different fractions, much less those with proteins within the ranges of the claimed "first" and "second" fractions. Note claims 27+ in particular.

Accordingly, no possible combination of these references suggests the claimed invention; therefore, the rejection should be withdrawn.

Claims 6 and 18 were rejected under 35 USC 103(a) as being unpatentable over Stevens in view of Liu et al and Furst et al. Furst et al does not compensate for the basic deficiency of Stevens and Liu et al and adds nothing to the primary teachings to render the independent claim obvious. Accordingly, this rejection should be withdrawn.

Claim 7 was rejected under 35 USC 103(a) as being unpatentable over Stevens in view of Liu et al and O'Donnell et al. O'Donnell et al does not compensate for the basic deficiency of Stevens and Liu et al and adds nothing to the primary teachings to render the independent claim obvious. Accordingly, this rejection should be withdrawn.

Claims 10, 11 and 19 were rejected under 35 USC 103(a) as being unpatentable over Stevens in view of Liu et al and Opiteck et al. Opiteck et al does not compensate for the basic deficiency of Stevens and Liu et al and adds nothing to the primary teachings to render the independent claim obvious. Accordingly, this rejection should be withdrawn.

Claims 15 and 16 were rejected under 35 USC 103(a) as being unpatentable over Stevens in view of Liu et al and Hage et al. Hage et al does not compensate for the basic deficiency of Stevens and Liu et al and adds nothing to the primary teachings to render the independent claim obvious. Accordingly, this rejection should be withdrawn.

In view of the above amendments and comments, the claims are now in conditions for allowance and applicants request a timely Notice of Allowance be issued in this application. If any issues or questions remain, the examiner is encouraged to call the undersigned at the telephone number below.

The commissioner hereby is authorized to charge payment of any fees under 37 CFR § 1.17, which may become due in connection with the instant application or credit any overpayment to Deposit Account No.500933.

Respectfully submitted,

Date: July 19, 2004

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